

## REMARKS

### The Office Action

Claims 83, 87, 88, 90, 101, 102, and 112 are pending in this application. Claims 1-82, 84-86, 89, 91-100, and 103-111 were previously canceled. Claim 113 has been added. Claim 83 stands rejected under 35 U.S.C. § 112, first paragraph, for reciting new matter. Claims 87, 88, 90, 101, 102, and 112 are objected to for their dependence on a rejected claim.

### Rejections Under 35 U.S.C. § 112, first paragraph

Claims 83 stands rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The Examiner asserts support is lacking for Z comprising (Lys)<sub>n</sub>. Applicants have addressed this rejection by amendment of the claim 83.

With respect to the definition of Z, claim 83 has been amended to remove the term “comprising” and to recite language which has explicit support in the specification.

In view of this amendment to claim 83, applicants request that the rejection for new matter be withdrawn.

### Support for the amendment to claim 83

With this reply claim 83 has been amended. Support for each of the added elements appearing in claim 83 is detailed below.

Support for a stabilizing peptide, Z, having from 4 to 15 amino acid residues, as recited in claim 83, is found in the specification at page 15, line 1.

Support for a stabilizing peptide, Z, having from 4 to 15 amino acid residues wherein Z comprises residues selected from Glu, Lys, and Met, as recited in claim 83, is found in the specification at page 13, lines 14-21, and page 14, line 2.

Support for (i)  $\text{Lys}_{4-10}$  units is found in the specification at page 16, lines 1-5.

Support for (ii)  $(\text{Lys-Xaa})_m$  is found in the specification at page 16, line 5.

Support for (iii)  $(\text{Xaa-Lys})_m$  is found in the specification at page 16, line 6.

Support for (iv)  $\text{Lys}_p\text{-Xaa}_q$  is found in the specification at page 16, line 12.

Support for (v)  $\text{Xaa}_p\text{-Lys}_q$  is found in the specification at page 16, line 13.

Support for (vi)  $\text{Xaa}^1\text{-Lys-Xaa}^2\text{-Lys}$  is found in the specification at page 16, lines 22-23.

Support for (vii)  $\text{Xaa}^1\text{-Lys-Xaa}^2\text{-Lys-Xaa}^2$  is found in the specification at page 16, line 23.

Support for (viii)  $\text{Xaa}^1\text{-Lys-Xaa}^2\text{-Lys-Xaa}^2\text{-Lys}$  is found in the specification at page 16, line 23.

Support for (ix)  $\text{Xaa}^1\text{-Xaa}^2\text{-Lys-Xaa}^2$  is found in the specification at page 16, line 23.

Support for (x)  $\text{Xaa}^1\text{-Xaa}^2\text{-Lys-Xaa}^2\text{-Lys}$  is found in the specification at page 16, line 24.

Support for (xi)  $\text{Xaa}^1\text{-Xaa}^1\text{-Lys-Xaa}^2\text{-Lys-Xaa}^2$  is found in the specification at

page 16, line 24.

Support for (xii) Lys-Xaa<sup>2</sup>-Lys-Xaa<sup>1</sup> is found in the specification at page 16, line 24.

Support for (xiii) Lys-Xaa<sup>2</sup>-Lys-Xaa<sup>2</sup>-Xaa<sup>1</sup> is found in the specification at page 16, lines 24-25.

Support for (xiv) Lys-Xaa<sup>2</sup>-Lys-Xaa<sup>2</sup>-Lys-Xaa<sup>1</sup> is found in the specification at page 16, line 25.

Support for (xv) Xaa<sup>2</sup>-Lys-Xaa<sup>2</sup>-Xaa<sup>1</sup> is found in the specification at page 16, line 25.

Support for (xvi) Xaa<sup>2</sup>-Lys-Xaa<sup>2</sup>-Lys-Xaa<sup>1</sup> is found in the specification at page 16, lines 25-26.

Support for (xvii) Xaa<sup>2</sup>-Lys-Xaa<sup>1</sup>-Lys-Xaa<sup>2</sup>-Xaa<sup>1</sup> is found in the specification at page 16, line 26.

Support for Xaa, Xaa<sup>1</sup>, and Xaa<sup>2</sup> selected from the group consisting of Ser, Thr, Tyr, Asn, Gln, Asp, Glu, Arg, His, and Met is found in the specification at page 16, lines 15-16 and 27-28.

Support for p and q is, independently, an integer from 1 to 14, with the proviso that p+q is from 4 to 15 is found in the specification at page 16, lines 13-14.

Support for m is an integer in the range from 2 to 7 is found in the specification at page 16, lines 5-7.

Support for Melanotan-II (MT-II, alpha-MSH4-10-NH<sub>2</sub>, or Ac-N<sup>1</sup>leu<sup>4</sup>-Asp<sup>5</sup>-His<sup>6</sup>-D-Phe<sup>7</sup>-Arg<sup>8</sup>-Trp<sup>9</sup>-Lys<sup>10</sup>) (SEQ ID NO: 32) as recited in claim 83 is found in the specification at page 11, lines 1-2.

Support for pharmacologically active peptide sequence X being selected from enkephalin, Leu-enkephalin, Met-enkephalin, angiotensin I, angiotensin II, vasopressin, endothelin, vasoactive intestinal peptide, neurotensin, endorphins, insulin, gramicidin, paracelsin, delta-sleep inducing peptide, gonadotropin-releasing hormone, human

parathyroid hormone (1-34), EMP-1, Atrial natriuretic peptide, human brain natriuretic peptide, cecropin, kinetensin, neurophysins, elafin, guamerin, atriopeptin I, atriopeptin II, atriopeptin III, deltorphin I, deltorphin II, vasotocin, bradykinin, dynorphin, dynorphin A, dynorphin B, growth hormone release factor, growth hormone, growth hormone releasing peptide, oxytocin, calcitonin, calcitonin gene-related peptide, calcitonin gene-related peptide II, growth hormone releasing peptide, tachykinin, adrenocorticotrophic hormone, cholecystokinin, corticotropin releasing factor, diazepam binding inhibitor fragment, FMRF-amide, galanin, gastric releasing polypeptide, gastric inhibitory polypeptide, gastrin, gastrin releasing peptide, glucagon, glucagon-like peptide-1, glucagon-like peptide-2, LHRH, melanin concentrating hormone, melanocyte stimulating hormone, alpha-MSH, morphine modulating peptides, motilin, neurokinin A, neurokinin B, neuromedin B, neuromedin C, neuromedin K, neuromedin N, neuromedin U, neuropeptide K, neuropeptide Y, pituitary adenylate cyclase activating polypeptide, pancreatic polypeptide, peptide YY, peptide histidine-methionine amide, secretin, somatostatin, substance K, thyrotropin-releasing hormone, kyotorphin, and melanostatin is found in the specification from page 9, line 20, to page 10, line 8. Applicants note that these peptides were previously the subject of claim 24, now canceled, which in the Office Action of September 5, 2001, the examiner found objectionable for including the term “or a modified or truncated fragment thereof” and in the Office Action of January 15, 2003, the examiner found objectionable for failure to find support for stabilizing peptide Z. Because claim 83 does not include the language “modified or truncated fragment thereof” in its description of pharmacologically active peptide X and defines stabilizing peptide Z in a manner for which there is explicit support in the specification, the addition of these pharmacologically active peptides to claim 83 does not raise any of the patentability issues previously identified by the Office with respect to this same subject matter as it appeared in claim 24, now canceled.

Support for a stabilizing peptide, Z, having from 4 to 7 amino acid residues

selected from Glu, Lys, and Met, as recited in new claim 113, is found in the specification at page 13, lines 18-21, and page 14, line 2.

### CONCLUSION

Applicants submit that the claims are now in condition for allowance and such action is respectfully requested. To expedite prosecution Applicants request a telephonic interview with the Examiner to discuss any remaining rejections. The Examiner is invited to call the undersigned at 617-428-0200.

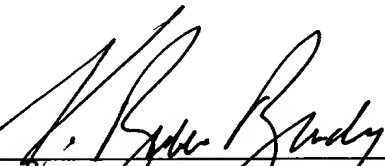
Enclosed is a Petition to extend the period for replying to the final Office action for three months, to and including July 30, 2006, and a check in payment of the required extension fee.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: \_\_\_\_\_

July 14, 2006

  
\_\_\_\_\_  
Kristina Bieker-Brady, Ph.D.  
Reg. No. 39,109

Clark & Elbing LLP  
101 Federal Street  
Boston, MA 02110  
Telephone: 617-428-0200  
Facsimile: 617-428-7045